Louisiana Medicaid
Pegvaliase-pqpz (Palynziq™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for pegvaliase-pqpz (Palynziq™).

*Pegvaliase-pqpz (Palynziq™) has a **Black Box Warning** and is available only through a restricted program under a **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to prescribing information for details.*

Pharmacy reimbursement of pegvaliase-pqpz (Palynziq™) requires a pharmacy claim for an auto-injectable epinephrine product within the previous year. If the auto-injectable epinephrine product is prescribed at the same time as pegvaliase-pqpz (Palynziq), the auto-injectable epinephrine claim must be submitted first.

Approval criteria for requests to initiate treatment with pegvaliase-pqpz (Palynziq™)

- The recipient is at least 18 years of age on the date of the request; **AND**
- The recipient has a diagnosis of phenylketonuria (PKU); **AND**
- The following is true and is **stated on the request:**
    - The recipient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management. [Existing management includes, but is not limited to dietary phenylalanine and/or protein restriction, and use of Kuvan (sapropterin dihydrochloride)]; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Pegvaliase-pqpz (Palynziq™) is prescribed by, or in consultation with, a healthcare provider experienced in the management of PKU; **AND**
    - The dose does not exceed the recommended dosing from the prescribing information; **AND**
    - Pegvaliase-pqpz (Palynziq™) and sapropterin dihydrochloride (Kuvan®) will not be used concomitantly; **AND**
    - The prescriber has prescribed an auto-injectable epinephrine prior to the first dose of pegvaliase-pqpz (Palynziq™), and the recipient (and observer if applicable) have been instructed on how to recognize and manage the signs and symptoms of anaphylaxis; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of pegvaliase-pqpz.

Reauthorization or Continuation Criteria:

- The recipient continues to meet initial approval criteria; **AND**
- The recipient has had a positive clinical response, shown by **ONE** of the following that is **stated on the request**:
    - The recipient has achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline; **OR**
    - The recipient's blood phenylalanine concentration is less than or equal to 600 micromol/L.

Duration of initial and reauthorization approval: 12 months

Reference

Palynziq (pegvaliase-pqpz) [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; Retrieved from https://www.palynziq.com/prescribinginformation.pdf